

**Amendment #1 (Questions & Responses)  
to RFP-NIH-NIAID-DMID-03-5**

**"Basic and Clinical Approaches to Controlling Human Respiratory  
Pathogens"**

<b>Amendment to Solicitation No.:</b>	<a href="#">RFP-NIH-NIAID-DMID-03-05</a>
<b>Amendment No.:</b>	1
<b>Amendment Date:</b>	September 17, 2002 (Questions 1-14) October 7, 2002 (Questions 15-17)
<b>RFP Issue Date:</b>	July 25, 2002
<b>Issued By:</b>	Jacqueline C. Holden Senior Contracting Officer NIH/NIAID Contract Management Branch 6700-B Rockledge Drive Room 2230, MSC 7612 Bethesda, Maryland 20892-7612
<b>Point of Contact:</b>	Nancy Hershey, Contracting Officer <a href="mailto:Nh11x@nih.gov">Nh11x@nih.gov</a>
<b>Name and Address of Offeror:</b>	To All Offerors

**THIS AMENDMENT PROVIDES QUESTIONS SUBMITTED BY OFFERORS AND THE RESPONSES PROVIDED BY THE NIAID PROJECT OFFICER. ANY FURTHER QUESTIONS AND THEIR RELATED RESPONSES WILL BE ADDED TO THIS AMENDMENT UPON RECEIPT. ALL OFFERORS SHOULD REFER BACK TO THIS AMENDMENT #1 FOR ADDITIONAL QUESTIONS AND RESPONSES.**

**Question 1:** Clarify the government's estimate of 24.9 FTE per year for part A and 19.9 FTE per year for part B contained on page 31. Is it possible that this is meant to be over the 7-year period of the award (3.57 FTE and 2.84 FTE per year, respectively)?

**Answer 1:** 32,936 hours/year for Part A; and 26,849/year hours for Part B. Additionally, as stated in the the RFP, this information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

**Question 2:** Clarify under Part A, the scope of work (I) includes a wide array of bacterial pathogens, but the required concept sheets (Note to Offerors 2) must focus on only four of them. The technical evaluation criteria (TEC) do not discuss the range of pathogens to be studied. One could conclude that pathogen-specific expertise in anything other than H. flu, S. pneumo, GAS, and N. mening is nice but really not needed - is that basically the concept? We can't think of a way that other pathogens can help the score given the way the RFP is structured.

**Answer 2:** We have clarified the requirements for Concept Papers under Part A (Notes to Offerors #2). For Part A, Offerors must provide as part of their proposal, 5 Concept Papers. One Concept Paper must focus on *Streptococcus pneumoniae*, one Concept Paper must focus on *Haemophilus influenzae*, and one Concept Paper must focus on group A streptococcus (GAS). The remaining two

Concept Papers can focus on any of the 10 bacterial pathogens listed under Part A, Section I; however, the Offeror should not submit more than 2 Concept Papers for any one bacterial pathogen.

**Question 3:** Do all of the collaborating institutions need to be identified in the letter of intent?

**Answer 3:** Yes, it is recommended that all collaborating institutions be identified on the letter of intent.

**Question 4:** Also, could you confirm that a collaborating institution can be a subcontractor to more than one primary applicant?

**Answer 4:** Yes.

**Question 5:** In the RFP, it states that NIAID is interested in *Haemophilus influenzae* type b. This is surprising as there is a very effective vaccine to this organism. Does this mean nontypeable *Haemophilus influenzae*?

**Answer 5:** The Statement of Work should have specified: *Haemophilus influenzae*. This would therefore include both *Haemophilus* type B and nontypeable *Haemophilus* strains.

**Question 6:** Must Bacterial Respiratory Pathogens Unit only be comprised of studies of bacterial agents or can some studies of viral agents be included?

**Answer 6:** While the major emphasis of the BRPRU will be on bacterial respiratory pathogens, some studies involving the interaction of bacterial and viral pathogens may be permitted per the work statement. For the BRPRU, Part A, Section II, area "a" indicates that the types of preclinical research activities that can be done under this contract includes studies on "polymicrobial interactions." For the BRPRU, polymicrobial interaction studies may include studies on bacterial-bacterial interactions and bacterial-viral interactions. The BRPRU will not support polymicrobial studies that focus only on viral-viral interactions.

**Question 7:** Can studies of polymicrobial infections (viral-bacterial) be included in both when considering colonization's and microbial interactions studies?

**Answer 7:** Yes.

**Question 8:** Must the Contractor have the studies on every organism listed under the bacterial pathogens group or can the proposal be limited to selected agents. If this is the case, which one must be included.

**Answer 8:** It is anticipated that the BRPRU contract will focus on studies of bacterial respiratory pathogens that are of highest programmatic importance to NIAID. For EVALUATION purposes only, NIAID has clarified the requirements for Concept Papers under Part A (Notes to Offerors #2). For Part A, Offerors must provide as part of their proposal, 5 Concept Papers. One Concept Paper must focus on *Streptococcus pneumoniae*, one Concept Paper must focus on *Haemophilus influenzae*, and one Concept Paper must focus on group A streptococcus (GAS). The remaining two Concept Papers can focus on any of the 10 bacterial pathogens listed under Part A, Section I; however, the Offeror should not submit more than 2 Concept Papers for any one bacterial pathogen.

**Question 9:** Can a viral and a bacterial contractor propose linked studies which would involve both centers?

**Answer 9:** As stated in the Introduction, the individual Bacterial and Viral Respiratory Pathogens Research Units will form a coordinated, multi-disciplinary network and NIAID will encourage the Principal Investigators of these units to work together on collaborative projects, along with the Principal Investigators of the Respiratory Pathogens Reference Laboratories.

For evaluation purposes only, an Offeror for a Bacterial Respiratory Pathogens Unit may propose as part of his proposal, collaborative studies that could be

undertaken with the Viral Respiratory Pathogens Unit. Conversely, an Offeror for a Viral Respiratory Pathogens Unit may propose as part of his proposal, collaborative studies that could be undertaken with the Bacterial Respiratory Pathogens Unit. If, for example, an Offeror planning to submit a proposal for a Bacterial Respiratory Pathogens Research Unit proposes collaborative studies with the Viral Respiratory Pathogens Research Unit, the major emphasis of the proposal should be on a bacterial pathogen(s). The viral component of the collaborative study should be emphasized if the Offeror is submitting a proposal for the Viral Respiratory Pathogens Research Unit.

**Question 10:** Is five the maximum number of Concept Papers or can the proposal have more than five?

**Answer 10:** Five is the maximum number of Concept Papers that can be submitted in the proposal for Part A. For Part B, the maximum number of Concept Papers is 6.

**Question 11:** Can core facilities be included in the Contract; for example - primary human airway epithelial cell core, a bacterial biofilm core, a core facility for performing airway epithelial cell gene expression profiles?

**Answer 11:** Yes; however all costs (personnel, materials, etc.) must be prorated for the proposed studies.

#### Other Clarifications

A separate budget that estimates the costs associated with the conduct of challenge studies should be provided as part of the proposal. **The offeror shall also specify how much notice they would need to arrange for personnel to support challenge studies.** The government reserves the right to fund challenge studies based on scientific need and as requested by the Project Officer.

**Question 12:** How many total awards will be made? The RFP says 3. Does this mean that there will be 3 Bacterial Respiratory Pathogen Research Units and 3 Viral Respiratory Pathogens Research Units, or a total of 3 (for example, 2 bacterial units and 1 viral unit, or 2 viral units and a bacterial unit)?

**Answer 12:** The Government anticipates 3 awards based on the best value to the Government.

**Question 13:** Can a Federal employee be a collaborator for this RFP? Specifically, would I be able to collaborate with someone at CDC? If so, could that person receive any funding (for example, for laboratory supplies) through this contract?

**Answer 13:** A federal employee can be a collaborator for this RFP, but not be paid from contract funds.

**Question 14:** I am currently the PI on an intramural contract for the evaluation of vaccines and other biologic agents. Am I allowed to compete for this contract?

**Answer 14:** You can compete for this contract as long as your commitment is not over 100% dedication to contracts and/or grants and that there is no overlap of salary support for personnel.

**Question 15:** I am in receipt of Amendment #1 and wanted to clarify that the response to question #1, resulted in a significant, 35% decrease in the estimated FTEs for the Part B award from 41,392 labor hours per year to 26,849 labor hours. This changes the scope of the project quite considerably, was this intended?

**Answer 15:** Yes. The approximate FTEs/year provided in the RFP were incorrect. The correct approximations were provided in Amendment #1.

**Question 16:** What provisions are made for generating challenge pools? Is this the responsibility of the investigator?

**Answer 16:** Some challenge materials manufactured by the Division of Microbiology and Infectious Diseases currently exist and may be available for clinical studies under the RPRN. Although production of additional challenge material may be supported under the BRPRU and the VRPRU, Offerors do not need to address their ability to generate challenge material in their proposal.

**Question 17:** Why does Part B with more concepts and more subjects to be enrolled in trials have a lower FTE allowance than Part A?

**Answer 17:** The submission of Concept Papers is for evaluation purposes only. Preclinical and clinical studies to be conducted will be determined by the Project Officer based on programmatic needs, priorities, and available resources.

- Except as provided herein, all terms and conditions of this RFP remain unchanged and in full force and effect.
- The hour and date specified for receipt of offers REMAINS: **November 18, 2002, 4:00 PM, EST.**
- Offerors must acknowledge receipt of this Amendment #1, on each copy of the proposal submitted.

*Failure to receive your acknowledgement of this amendment may result in the rejection of your offer.*

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